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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/769,695 | 01/30/2004 | Shubh D. Sharma | 70025-US04-129 | 8611 |

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| EXAMINER | |
|---|---|
| KAM, CHIH MIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1656 | |

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/769,695 | SHARMA ET AL. | |
| | Examiner | Art Unit | |
| | Chih-Min Kam | 1656 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1-9 (in part) and 10-21, drawn to a method for determining the specific residues binding to a target of interest within a known primary sequence parent polypeptide consisting of n residues that binds to the target of interest by complexing a peptide of the formula $R_1$-Z-$R_2$ to a metal ion to form $R_1$-Z-$R_2$ metallopeptide, and screening $R_1$-Z-$R_2$ metallopeptide for binding to the target of interest, where Z is a residue having a nitrogen atom and a sulfur atom and is inserted between two adjacent residues in the primary structure of the known parent peptide and the number of residues in $R_1$-Z-$R_2$ is equal n+1, or by making a series of peptides, wherein each peptide includes the known primary sequence of the parent polypeptide and a single inserted L- or D-3-mercapto amino acid residue, complexing each peptide in the series with a metal ion to form a series of metallopeptides, and determining the binding of each metallopeptide in the series to the target of interest, classified in class 514, subclass 6, and class 435, subclass 7.1.

II. Claims 1-9 (in part) and 22-33, drawn to a method for determining the specific residues binding to a target of interest within a known primary sequence parent polypeptide consisting of n residues that binds to the target of interest by complexing a peptide of the formula $R_1$-Z-$R_2$ to a metal ion to form $R_1$-Z-$R_2$ metallopeptide, and screening $R_1$-Z-$R_2$ metallopeptide for binding to the target of interest, where Z is a residue having a nitrogen atom and a sulfur atom and is substituting for a single residue

corresponding to a single residue in such primary structure and the number of residues in $R_1$-Z-$R_2$ is equal n, or by making a series of peptides, wherein each peptide includes the known primary sequence of the parent polypeptide with a single substitution by L- or D-3-mercapto amino acid residue, complexing each peptide in the series with a metal ion to form a series of metallopeptides, and determining the binding of each metallopeptide in the series to the target of interest, classified in class 514, subclass 6, and class 435, subclass 7.1.

III. Claims 34-37, drawn to a metallopeptide library for determining the specific residues binding to a target of interest within a known primary sequence parent polypeptide of at least 5 residues that binds to the target of interest, comprising a series of metallopeptides, wherein each metallopeptide includes the known primary sequence of the parent polypeptide, a single inserted L- or D-3-mercapto amino acid residue and a metal ion complexed to the sequence comprising the single inserted L- or D-3-mercapto amino acid and the two residues on the immediately adjacent N-terminus side of the single inserted L- or D-3-mercapto amino acid residue, classified in class 514, subclass 6, and class 435, subclass 7.1.

IV. Claims 38-41, drawn to a metallopeptide library for determining the specific residues binding to a target of interest within a known primary sequence parent polypeptide of at least 5 residues that binds to the target of interest, comprising a series of metallopeptides, wherein each metallopeptide includes the known primary sequence of the parent polypeptide with a single substitution by L- or D-3-mercapto amino acid residue and a metal ion complexed to the sequence comprising the single substituent L-

or D-3-mercapto amino acid and the two residues on the immediately adjacent N-terminus side of the single substituent L- or D-3-mercapto amino acid residue, classified in class 514, subclass 6, and class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

The product of Invention III and the method of Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention IV can be used in the method of Invention I.

The product of Invention IV and the method of Invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Invention III can be used in the method of Invention II.

The methods of Inventions I and II are distinct from each other because the method steps and the materials used are different in Inventions I and II.

The products of Inventions III and IV are distinct from each other because the metallopeptide library of two inventions contain different metallopeptides, e.g., Invention III contains metallopeptides with n+1 residues, while Invention IV contain metallopeptides with n residues.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, and because inventions I-IV require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: a receptor, antibody, toxin, enzyme, hormone, nucleic acid, intracellular protein domain of biological relevance or extracellular protein domain of biological relevance (claims 5, 18 and 30). Due to the distinctness in chemical structure and function, a search for one compound would not necessarily overlap with another. Thus requiring an individual search should be conducted for each species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species therefrom for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, for Group I, claims 5 and 18 are generic; and for Group II, claims 5 and 30 are generic.

Applicant is advised that a reply to this requirement must include an identification and structure for the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §

821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
April 29, 2006